663 · John E Klemmer, C.O. 7-24-97

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Detroit District
1560 E. Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

July 25, 1997

WARNING LETTER
97-DT-11

Byron B. Buhner
Responsible Head
Central Indiana Regional Blood Center
3450 N. Meridian Street
Indianapolis, Indiana 46208

Dear Mr. Buhner:

An inspection of your facility was conducted on June 16 - 30, 1997 by the Food and Drug Administration. The inspection revealed significant deviations from Current Good Manufacturing Practice Regulations for Blood and Blood Products, Title 21, Code of Federal Regulations, Part 606 and 640 (21 CFR 606 and 640), and Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR Part 211). These deviations cause your licensed product, Whole Blood, to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), Section 501(a)(2)(B), as follows:

> Failure to follow Standard Operating Procedures (SOPs)[21 CFR 606.100(b) and 211.100(b)] in that:
>
> a. initially reactive viral marker tests are not always repeated in duplicate;
>
> b. there is not always written documentation of investigation of failed external controls for viral marker tests;
>
> c. written documentation of investigation and corrective action for failed viral marker test runs is not always complete.

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your center is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as license suspension and/or revocation, seizure and/or injunction.

We acknoledge receipt of your July 9, 1997 response to the inspectional observations, however, we find the response incomplete. Your response to observations 1a regarding the 5/5/97 HBC run indicates that this run was not included in recall actions due to the fact that the technologist removed the acid from the run when it was discovered that the external control had failed, although this fact was not documented. The fact that the technologist retrospectively documented the event, and has had few failed/suspect runs is insufficient evidence to exclude this batch from some form or corrective action.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Mrs. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,

John P. Dempster
for Raymond V. Mlecko
Acting District Director
Detroit District

cc: Mrs. Mary Azvill, Director
Indiana State Department of Health
Acute Care Service Division
1330 West Michigan Street
P.O. Box 1964
Indianapolis, Indiana 46206-1964